

## Laboratory analysis of valsartan products

FDA continues to investigate the presence of impurities in valsartan and other angiotensin II receptor blockers (ARBs) used to treat high blood pressure and heart failure. FDA has identified the impurities N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in ARB active pharmaceutical ingredient (API) and finished drugs. Medicines with confirmed levels of NDMA or NDEA exceeding the interim acceptable intake limits ([/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan](#)) have been recalled ([/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and](#)) because they pose an unacceptable safety risk to patients.

FDA is posting additional test results in the table below showing NDMA and NDEA levels in recalled valsartan. The analyses reflect average levels of the impurities present in a single tablet based on the strength of the tested medicines within the lots tested, which are identified in the table. The table provides NDMA and NDEA levels and indicates where impurities either were not present or were below the limit of detection (LOD) of our testing method. Some of the medicines listed below may have been repackaged by other companies as noted in FDA's list of recalled ARBs ([/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and](#)).

Based on FDA laboratory testing results and records from manufacturers of the recalled valsartan lots, the impurities may have been present in valsartan-containing finished drug lots for up to four years. FDA based the estimates below on the highest daily dose; however, many people may have taken lower doses, and therefore, their risks would theoretically be less. FDA expects the actual cancer risk to most consumers to be lower than our estimate. For reference, consuming up to 0.096 micrograms of NDMA or 0.0265 micrograms of NDEA per day is considered reasonably safe for human ingestion based on lifetime exposure.

### NDMA ESTIMATED RISK:

FDA estimated that if 8,000 people took the highest valsartan dose (320 mg) containing NDMA from the recalled batches daily for four years, there may be one additional case of cancer over the lifetimes of the 8,000 people.

### NDEA ESTIMATED RISK

FDA scientists estimate that if 18,000 people took valsartan at the highest dose (320 mg) containing NDEA from recalled batches daily for four years, there may be one additional case of cancer over the lifetime of these 18,000 people. NDEA has a marginally lower cancer risk estimate than NDMA because NDEA levels were lower than levels of NDMA in drug samples.

Company	Product (tablets)	Lots Tested	NDMA level (micrograms -mcg/tablet)	NDEA level (micrograms -mcg/tablet)
Aurobindo Pharma Ltd	Amlodipine 10mg/Valsartan 320 mg	VKSA18005-A, VKSA18007-A, VKSA18001-A	Below LOD	0.02-0.09
Aurobindo Pharma Ltd	Valsartan 320mg	VUSD17008-A, VUSD17001-A, VUSD17009-A	Below LOD	0-0.05
Aurobindo Pharma Ltd	Valsartan 320mg/HCT 25mg	HTSB18001-A, HTSB18028-A, HTSB18029-A	Below LOD	0.02-0.19
Hetero Labs Ltd	Valsartan 320mg	VLS18049, VLS18051, VLS18050	0.33-0.44	Below LOD
Mylan Pharmaceutical Inc.	Amlodipine 10mg/Valsartan 320 mg	3079709, 3077618, 3079708	Below LOD	0.04-0.11
Mylan Pharmaceutical Inc.	Amlodipine 10mg/Valsartan 320 mg/HCT 25mg	2008702	Below LOD	0.05
Mylan Pharmaceutical Inc.	Valsartan 320mg	3080009, 3080010, 3079205	Below LOD	0.07-0.16
Mylan Pharmaceutical Inc.	Valsartan 320mg/HCT 25mg	3084886, 3093804, 3084862	Below LOD	0.20-0.38
Princeton Pharmaceutical	Valsartan 320mg	344B18027, 344B18028, 344B18029	15.18-16.30	Below LOD
Princeton Pharmaceutical	Valsartan 320mg/HCTZ 25mg	611B18025, 611B18026, 611B18027	13.18-20.19	Below LOD
Teva Pharmaceutical	Amlodipine 10mg/Valsartan 320 mg	26X053, 26X054, 26X055, 26X051, 26X044, 26X048	Below LOD	0-0.03

Teva Pharmaceutical	Amlodipine 10mg/Valsartan 320 mg/HCT 25mg	22X045, 22X046, 22X047, 22X038, 22X041	Below LOD	0-0.03
Teva Pharmaceuticals	Valsartan 320mg	1240425A, 1247282M	7.92-16.55	Below LOD
Teva Pharmaceuticals	Valsartan 320mg/HCTZ 25mg	1217576M, 1217577M, 1217578M	6.94-10.35	0-0.77
Torrent Pharmaceuticals	Amlodipine 10mg/Valsartan 320 mg/HCTZ 25mg	BBX2E001, BBX2E002, BBX2E003	10.24-11.53	Below LOD
Torrent Pharmaceuticals	Valsartan 320mg	BV48D001, BV48D002	0.56-0.62	1.12-1.22
Torrent Pharmaceuticals	Valsartan 160mg	BV47D001	0.45	1.31